

against disease caused by infection by respiratory syncytial (RS) virus, which comprises:

growing RS virus on a continuous cell line of vaccine quality to produce a grown virus;

*(J)*  
*cont'd*  
harvesting said grown virus to produce a harvested virus;

purifying said harvested virus under non-denaturing conditions to produce a purified virus [substantially] free from cellular and serum components;

inactivating said purified virus with an inactivating agent to provide a non-infectious, non-immunopotentiating and protective [immunogenic] RS viral preparation, and

formulating said non-infectious, non-immunopotentiating and protective [immunogenic] RS viral preparation as a vaccine [said immunogenic composition].

12. (Twice Amended) A method of preparing a non-immunopotentiating vaccine capable of protecting a human host immunized therewith against disease caused by infection by respiratory syncytial (RS) virus, which comprises:

*(C3)*  
growing RS virus on a continuous cell line of vaccine quality to produce a grown virus;

harvesting said growth virus to produce a harvested virus;

purifying said harvested virus under non-denaturing conditions to produce a purified virus substantially free from cellular and serum components [The method of claim 5 wherein said purifying step is effected] by:

(i) microfiltration to remove cell debris,

(ii) tangential flow ultrafiltration to remove serum components and provide a retentate,

(iii) pelleting the retentate by ultracentrifugation to further remove serum components, and

*(C3  
Conc)*

(vi) subjecting the pelleted material to sucrose density gradient centrifugation;  
inactivating said purified virus with an inactivating agent selected from the group consisting of  $\beta$ -propiolactone, a non-ionic detergent which is n-octyl- $\alpha$ -D-glucopyranoside or n-octyl- $\beta$ -D-glucopyranoside, and ascorbic acid, to provide a non-infectious, non-immunopotentiating and protective RS viral preparation, and  
formulating said non-infectious, non-immunopotentiating and protective RS viral preparation as a vaccine.

14. (Amended) A method of preparing a non-immunopotentiating vaccine capable of protecting a human host immunized therewith against disease caused by infection by respiratory syncytial (RS) virus, which comprises:

growing RS virus on a continuous cell line of vaccine quality to produce a grown virus;  
harvesting said growth virus to produce a harvested virus;

*(C4)*  
purifying said harvested virus under non-denaturing conditions to produce a purified virus substantially free from cellular and serum components [The method of claim 5 wherein said purifying step is effected] by:

(i) microfiltration to remove cell debris,  
(ii) tangential flow ultrafiltration to remove serum components,  
(iii) gel filtration to further remove serum components, and  
(vi) ion-exchange chromatography to additionally remove serum components;  
inactivating said purified virus with an inactivating agent selected from the group consisting of  $\beta$ -